

demonstrate that mastitis in dairy cows is prevented by administering feedstuff comprising phytase to dairy cows. Note, in particular, that treatment reduces the number of somatic cells (Examples 1, 2 and 3) in animals with light mastitis. See also Example 7 where 50 dairy cows were maintained on feed according to Example 6. The results plainly show a statistically compelling result where mastitis was prevented from just two weeks administration of phytase. Specification page 15, lines 4-7.

(2) 35 U.S.C. 112, first paragraph

Claim 9 is amended to change "lactating cows" 9 to "the dairy cows" as kindly suggested by the Examiner.

(3) 35 U.S.C. 112, second paragraph

Claim 1 is amended to add --for--, following the Examiner's indication.

(4) 35 U.S.C. 102(b)

The Examiner states that Lyons and Bedford teach administering phytase to "cows/cattle," and since "cows" that give milk are "dairy cows," claim 9 is substantially identical to the processes described in the references. This rejection is respectfully traversed.

As described previously, claim 9 is amended to recite a method for preventing mastitis in dairy cows that exhibit increased numbers of somatic cells in their milk. After such cows are selected, feedstuff comprising phytase is administered thereto.

In contrast, Lyons describes that concentration of inorganic phosphate in the feces of swine is decreased by administering phytase, so as to reduce environmental pollution. However, swine are monogastric. Thus, Lyons does not describe administering feedstuff containing phytase to "dairy cows" (claim 9) or for that matter, ruminants (claim

1). Nor does Lyons teach or suggest selecting cows with increased numbers of somatic cells in their milk.

In any event, since the rumen microbes present in ruminants, including cows, already produce phytase (see from specification page 2, line 23 to page 3, line 1), there is plainly no motivation to administer feedstuff containing additional phytase in order to decrease inorganic phosphate concentrations in the feces.

As to Bedford, such discloses that phytase enzyme-containing feedstuff can be administered to "cows," but does not disclose a method including a step of selecting cows with increased numbers of somatic cells or any method of preventing mastitis in dairy cows.

(5) 35 U.S.C. 102(e)

The Examiner states that Clarkson and Morgan teach administering phytase to "cows/cattle" and since "cows" that give milk are "dairy cows," claim 9 is substantially identical with that described in the references. This is essentially the same rejection as was made over Lyons and Bedford, but under a different statutory provision.

Again, neither reference teaches or suggests the step of selecting cows with increased numbers of somatic cells in their milk, or any method of preventing mastitis in dairy cows.

(6) 35 U.S.C. 102(b)

Again, referring to claim 9, the Examiner states Edwards teaches administering phytase to "cows/cattle" and that "cows" that give milk are "dairy cows." The salient feature of Edwards differing from Lyons and Bedford (point 4 above) and Clarkson and Morgan (point 5 above) is that Edwards describes phytase contained in the feedstuff at 30 to 600 unit/kg.

Edwards discloses a method for promoting use of phytic acid by administering feedstuff supplemented with vitamin D3 derivative and phytase. However, Edwards does not teach or suggest a step of selecting cows with increased numbers of somatic cells in their milk, or any method of preventing mastitis in dairy cows.

(7) 35 U.S.C. 103(a)

The Examiner states that the methods of claims 1-3, 7-10, 12 and 13 of the present application would have been obvious over each of Lyons, Clarkson, Morgan and Bedford in view of Edwards and Chinese Patent No. 1135297 (Lu). This rejection is respectfully traversed as follows.

Specifically, Lyons, Clarkson, Morgan and Bedford do not disclose a method including administering a feedstuff containing a therapeutically effective amount of phytase for treating mastitis in ruminants, or for preventing mastitis in dairy cows. Edwards clearly describes phytase is administered in an amount sufficient to enhance phytase phosphorous utilization in order to reduce dietary calcium and phosphorous supplementation, e.g., to lesson feed costs (column 5, lines 1-5). Moreover, Lu clearly describes that zinc methionine sulfate is a common additive for bullfrog feed to improve the shelf life of the resulting feedstuff.

Although the Examiner states that it would have been obvious to use such a feedstuff to treat "animals suffering from mastitis since many cows develop mastitis

regularly”, and contends it is “inevitable that the farmer who feeds all of his cows with the feedstuff will also feed [the feedstuff to] cows with mastitis and thus they will be treated,” the former is off-point and the latter is simply untrue. First, it is stipulated that it is necessary to treat mastitis in suffering animals. However, the only relevant inquiry is whether or not it would have been obvious to treat those animals with phytase. Plainly, it would not have been.^{1/}

While Lyons, Clarkson, Morgan and Bedford disclose feedstuff supplemented with phytase and some of these may even suggest such feedstuff can be administered to cows or cattle, no reference of record teaches or suggests that adequate quantity of phytase has any effect on mastitis. Accordingly, these references cannot possibly render obvious a process that involves administering a therapeutically effective amount of phytase to ruminants that suffer from mastitis (claim 1) or selecting a dairy cow that exhibits an increased number of somatic cells in her milk (claim 9).

Nor are these deficiencies addressed by the secondary references. Accordingly, as discussed below in greater detail, the Examiner has not made out a prima facie case of obviousness.

As mentioned previously, Edwards discloses a method for promoting the use of phytic acid by administering feedstuff supplemented with vitamin D3 derivative and phytase. Phytase is contained at 30 to 600 unit/kg, and “cattle” are among a laundry list of suitable animals to which the feed can be administered. However, Edwards but does not disclose a method for treating mastitis, does not teach administering therapeutic amounts of phytase to ruminants that suffer from mastitis, does not disclose a method for preventing

^{1/} The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. That which may be inherent is not necessarily known, and obviousness cannot be predicated on what is unknown. Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. In re Rijckaert 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

mastitis in "dairy cows", and does not teach selecting dairy cows having an increased number of somatic cells in their milk.

Lu describes a feedstuff that has been supplemented with zinc methionine sulfate. However, Lu does not disclose a method for treating mastitis, does not teach administering therapeutic amounts of phytase to ruminants that suffer from mastitis, does not disclose a method for preventing mastitis in "dairy cows", and does not teach selecting dairy cows having an increased number of somatic cells in their milk. Accordingly, there is no prima facie case of obviousness.

In any event, as conclusively shown in Table 3 at specification page 11, dairy cows of the phytase-administered group showed a significantly reduced number of somatic cells in their milk (150,000 cells/ml) at 1 month following the start of administration, while dairy cows of the zinc methionine sulfate-administered control group according to Lu showed at least 200,000 cells/ml.

This remarkable (25%) improvement is neither taught nor suggested by any of the prior art. Indeed, this result is necessarily surprising to those of ordinary skill, since it is well-understood that ruminants, such as cows, have rumen microbes which themselves produce phytase (specification page 2, lines 15-22), so it is entirely unexpected that added phytase would have any material effect. See from specification page 2, line 23 to page 3, line 1. For these reasons alone, any prima facie case of obviousness is necessarily overcome.

Indeed, since ruminants already have rumen microbes producing phytase, the prior art teaches away from administering apparently unnecessary additional (and costly) phytase to ruminants for any reason, and certainly does not teach any reason to do so in order to treat ruminants suffering from mastitis, or selecting dairy cows with an increased number of somatic cells in their milk.

(8) 35 U.S.C. 103(a)

The Examiner acknowledges that Edwards does not teach either using feedstuff supplemented with zinc methionine sulfate, or using any feedstuff for treating or preventing mastitis. However, the Examiner states Lu clearly describes that zinc methionine sulfate is a common feed additive for animals, that the addition of zinc methionine sulfate to feedstuff improves the shelf life of the feedstuff and again argues such feedstuff would inherently have treated mastitis, e.g., since many cows develop mastitis regularly, the Examiner contends any farmer who feeds the feedstuff to all of his cows will also inevitably feed the feedstuff to cows with mastitis, so that such cows will be treated.

Although the factual bases of this rejection are respectfully traversed, the rejection necessarily fails at least because Edwards does not teach or suggest selecting a dairy cow that exhibits an increased number of somatic cells in her milk (claim 9). Moreover, Edwards does not teach administering a therapeutically effective amount of phytase so as to treat mastitis (claim 1). In any event, the inherency argument is entirely without basis in the law since it is clear that all ruminants do not suffer from mastitis. In re Rijckaert, supra.


CONCLUSION

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-3, 7-10, 12 and 13 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


Attorney for Applicants
Lawrence S. Perry
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200



VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

1. (Twice Amended) A method for treating mastitis in [mammals excluding humans] a ruminant that suffers from mastitis, which comprises administering a therapeutically effective amount of phytase to [mammals] said ruminant [that suffer from mastitis].

9. (Twice Amended) A method for preventing mastitis in a dairy cow[s], which comprises selecting a dairy cow that exhibits an increased number of somatic cells in her milk, and administering feedstuff comprising a therapeutically effective amount of phytase to said dairy [lactating] cow[s].

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